

# Biosafety Risk Assessment

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## Biosafety Risk Assessment

### 1. Characterize biological agents and laboratory activities

- Evaluate the specific biologic agent hazards
- Evaluate laboratory procedure hazards
- Evaluate in-place hazard mitigation measures

### 2. Evaluate scenarios

- Create scenarios consisting of the specific agent and specific laboratory procedures
- Determine the likelihood of exposure based upon the procedure and the likelihood of infection based upon the agent as related to the method of exposure

### 3. Characterize the risk

- Evaluate the overall likelihood and consequences of each scenario
- Determine acceptable and unacceptable risks; develop risk statement





## Class Activity: Brainstorming Risk Assessment Criteria

- On the worksheet, list criteria that you think would be important for biosafety risk assessment
  - Identify whether each criterion impacts the likelihood (probability), consequences, or both for biosafety risks
  - If you were doing a risk assessment, identify who you might have help you evaluate each criterion
- Example:

Criterion	Biosafety			Biosecurity			Who would you ask for help in evaluating this criterion?
	L	C	Both	L	C	Both	
Biological Agents							
4. Morbidity		x			x		scientist
5. Mortality		x			x		scientist
6. Routes of Infection	x			x			scientist



## Biosafety Risk Assessment: Characterize the Biological Agents

- What is known about the agent?
  - Pathogenicity – ability to cause disease
  - Virulence – degree of pathogenicity
  - Host range – restricted or broad, human, animals, plants
  - Communicability – are there reports of epidemics? Of laboratory infections?
  - Transmission – means (e.g., direct contact, vector borne) and routes (e.g., ingestion, inhalation)
  - Environmental stability – e.g., resistance to disinfection
- Additional agent factors:
  - Toxicity
  - Is the agent associated with cancer (e.g., Hepatitis B virus associated with liver cancer)?
  - Does the agent or by-products induce allergic reactions (e.g., Penicillin)?



## Biosafety Risk Assessment: Characterize the Laboratory Procedure Hazards

- **Does the environment or activity change the risk?**
  - Laboratory versus field studies
  - Animal studies?
  - Procedures
    - Do planned experiments have the potential to generate aerosols?
  - Equipment
    - Needles
    - Centrifuges
    - Homogenizers
    - Pipettes



## Biosafety Risk Assessment: Consider Personnel Doing the Work

- **Are their host factors that change the risk?**
  - Deficiencies in host defenses
    - **Pre-existing medical conditions – for example:**
      - Asplenia, eczema
  - Reproductive hazards
    - **Pregnancy, teratogens, mutagens – for example:**
      - Rubella, *Toxoplasma*, *Chlamydia*
  - Allergies
    - **Foreign proteins, vaccine constituents, antimicrobial therapies – for example:**
      - Animal dander, egg proteins, latex
  - Immunization status
    - **Immunization against workplace pathogens, but ...**
      - Not always the answer (vaccine efficacy, safety issues)
  - Behavioral elements
    - **Education, training, experience, motivation, attentiveness**



## Biosafety Risk Variables in More Detail

**Biosafety Risk = F (Likelihood)(Consequence of Disease)**

**Consequence of Disease = F (Biological Properties of Agent) ( Mitigation Measures )**

**Likelihood = F (Likelihood of Exposure)(Likelihood of Infection)**

**Likelihood of infection = F (Biological Properties of Agent)**

**Likelihood of Exposure = F ( Laboratory Hazards ) ( Biosafety Practices )**